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11/18/03

PATENT APPLICATION DOCKET NO.: 1440.2032-001

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Robert J. Thomas and Robert W. Daly

Title:

GAS SYSTEMS AND METHODS FOR ENABLING RESPIRATORY

**STABILITY** 

Date: 11/18/03

EXPRESS MAIL LABEL NO. EN 215129811 US

## <u>INFORMATION DISCLOSURE STATEMENT</u>

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:	
This I	nformation Disclosure Statement is submitted:
[ ]	under 37 CFR 1.129(a), or (First/Second submission after Final Rejection)
[x]	under 37 CFR 1.97(b), or (Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including CPA, or a Request for Continued Examination).
[]	under 37 CFR 1.97(c) together with either:  [ ] a Statement under 37 CFR 1.97(e), as checked below, or  [ ] a \$180.00 fee under 37 CFR 1.17(p), or  (After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
[]	under 37 CFR 1.97(d) together with:  [ ] a Statement under 37 CFR 1.97(e), as checked below, and  [ ] a \$180.00 fee under 37 CFR 1.17(p), or  (Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
[ ]	under 37 CFR 1.97(i): Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper. (Filed after payment of issue fee)

Statem	<u>ien</u>	t Une	ier 3/	<u>_FR 1.97(e)</u>		
[ ]	Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or					
[]	No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.					
Statem	<u>ien</u>	t Uno	der 37 (	(Patent Term Adjustment) Applies to original applications (other than design) filed on or after May 29, 2000		
[ ]	cc W	mmı as no	unication treceive	information contained in the Information Disclosure Statement was cited in a son from a foreign patent office in a counterpart application and this communication yed by any individual designated in § 1.56(c) more than thirty days prior to the aformation Disclosure Statement.		
[X]	Eı	nclos	ed here	with is form PTO-1449:		
	[X]		Copies	s of the cited references are enclosed.		
			[X]	Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.		
	[	]	Applic	s of the cited references are enclosed except those entered in prior application, U.S. eation No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier ation contains copies of the cited references.]		
	[	]	The list	sted references were cited in the enclosed International Search Report in a rpart foreign application.		
	[	]	The "c	oncise explanation" requirement (non-English references) for reference(s) [ 37 CFR 1.98(a)(3) is satisfied by:		
			[ ]	the explanation provided on the attached sheet.		
			[ ]	the explanation provided in the Specification.		
			[ ]	submission of the enclosed International Search Report.		
			[ ]	submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.		
			f 1	the enclosed English language abstract.		

[]	Appl	licant requests that the following r	non-published pending appli	cations be considered:
Examiner's Initials	5			
	-	U.S. Patent Application No. [	], by [inventor(s)], filed [	], Docket No.: [ ]
	-	U.S. Patent Application No. [	], by [inventor(s)], filed [	], Docket No.: [ ]
	-	U.S. Patent Application No. [	], by [inventor(s)], filed [	], Docket No.: [ ]
		Examiner	Date	_
	[ ]	A copy of each above-cited app	olication, including the curre	ent claims, is enclosed.
	[ ]	A copy of each above-cited app those entered in prior application 35 U.S.C. 120 is claimed.	olication, including the curre on, U.S. Application No. [	ent claims, is enclosed, except ], to which priority under
		er is requested to return a copy of ere considered with the next offic		plications indicating which
It is re	queste	ed that the information disclosed h	erein be made of record in t	his application.
Metho	od of p	ayment:		
[ ]		eck for the fee noted above is encl mpanying Reply. A copy of this S		cluded in the check with the
[]	Pleas enclo	se charge Deposit Account 08-038 osed.	0 in the amount of \$[	. A copy of this Statement is
[X]	Pleas	se charge any deficiency in fees an	d credit any overpayment to	Deposit Account 08-0380.
		F	Respectfully submitted,	
		F	HAMILTON, BROOK, SMI	TH & REYNOLDS, P.C.
		E	Mary Lou Wakimura Registration No.: 31,804 Telephone: (978) 341-0036 Facsimile: (978) 341-0136	Kein

Concord, MA 01742-9133 Dated: UUU

## INFORMATION DISCLOSURE CITATION IN AN APPLICATION

November 18, 2003

(Use several sheets if necessary)

ATTORNEY DOCKET NO. 1440.2032-000	APPLICATION NO.
APPLICANT	

Robert J. Thomas et al.

FILING DATE CONFIRMATION NO. GROUP

		U.S. PATENT DOCUMENTS						
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME				
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EXAMINER	DATE CONSIDERED

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PTO-1449 REPRODUCED	ATTORNEY DOCKET NO. 1440.2032-000	APPLICATION NO.	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	APPLICANT Robert J. Thomas et al.		
November 18, 2003  (Use several sheets if necessary)	FILING DATE	CONFIRMATION NO.	GROUP
(Use several sheets if necessary)			

	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
AR	Lorenzi-Filho, G. et al., "Effects of Inhaled Carbon Dioxide and Oxygen on Cheyne-Stokes Respiration in Patients with Heart Failure," American Journal of Respiratory Critical Care Medicine 159:1490-1498 (1999).
AS	Javaheri, S. and W.S. Corbett, "Association of Low PaCO <sub>2</sub> with Central Sleep Apnea and Ventricular Arrhythmias in Ambulatory Patients with Stable Heart Failure," <i>Annals of Internal Medicine 128</i> :204-207, 2/1/98.
АТ	Xie, A. et al., "Apnea-Hypopnea Threshold for CO <sub>2</sub> in Patients with Congestive Heart Failure," American Journal of Respiratory Critical Care Medicine 165(9):1245-50, 5/1/02.
AU	Topor, Z.L. et al., "Dynamic ventilatory response to CO(2) in congestive heart failure patients with and without central sleep apnea," <i>J. Appl. Phys.</i> 91(1):408-16, July 2001.
AV	Nattie, E., "CO <sub>2</sub> , Brainstem Chemoreceptors and Breathing," <i>Progress in Neurobiology</i> 59(4):299-331, Nov. 1999.
AW	Javaheri, S., "A Mechanism of Central Sleep Apnea in Patients with Heart Failure," <i>The New England Journal of Medicine 341(13)</i> :949-54, September 23, 1999.
AX	Xie, A. et al., "Effects of inhaled CO2 and added dead space on idiopathic central sleep apnea," J. Appl. Physiol., 82(3):918-26, March 1997.
AY	Xie, A. et al., "Hypocapnia and Increased Ventilatory Responsiveness in Patients with Ideopathic Central Sleep Apnea," <i>American Journal of Respiratory and Critical Care Medicine</i> , 152(6 Pt 1):1950-5, December 1995.
AZ	Badr, M.S. "Treatment of Refractory Sleep Apnea with Supplemental Carbon Dioxide," American Journal of Respiratory and Critical Care Medicine 150(2):561-4, August 1994.
AR2	Thalhofer S. and P. Dorow, "Sleep-Breathing Disorders and Heart Failure," Sleep and Breathing 4:(3)103-111, 2000.
AS2	Teschler, H. et al., "Adaptive Pressure Support Servo-Ventilation: A Novel Treatment for Cheyne-Stokes Respiration in Heart Failure," <i>American Journal of Respiratory Critical Care Medicine</i> 164:614-619, 2001.

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EXAMINER	•	DATE	CONSIDERED	

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		OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
-	· · · · · · ·	OTHER DOCUMENTS (Including Author, Title, Date, Fertinent Fages, Etc.)
	AT2	Krachman S.L. et al., "Comparison of Oxygen Therapy with Nasal Continuous Positive Airway Pressure on Cheyne-Stokes Respiration During Sleep in Congestive Heart Failure," <i>Chest 116</i> :1550-1557, 1999.
	AU2	Lorenzi-Filho, G. et al., "Effects of Inhaled Carbon Dioxide and Oxygen on Cheyne-Stokes Respiration in Patients with Heart Failure," <i>American Journal of Respiratory Critical Care Medicine 159</i> :1490-1498, 1999.
	AV2	Pack A.I. et al., "Modafinil as Adjunct Therapy for Daytime Sleepiness in Obstructive Sleep Apnea," <i>American Journal of Respiratory Critical Care Medicine 164</i> :1675-1681, 2001.
	AW2	Francis, D.P. et al., "Quantitative General Theory for Periodic Breathing in Chronic Heart Failure and its Clinical Implications," <i>Circulation</i> 102(18):2214-2221, October 31, 2000.
	AX2	
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EXAMINER	DATE CONSIDERED